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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,759	08/16/2005	Gary Mark Coppola	4-32859A	1610

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
MABRY, JOHN	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,759	COPPOLA ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that claim 36, 37, 38 and 39 are "use" claims. For example, claim 38 provides for the use of "the compound according to claim 1, for the preparation of a pharmaceutical composition for treating a associated with 11β-HSD1 Oxoreductase activity", but, since the claim does not set forth any steps involved in the method or process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). "Use" claims pending at the time of the first action on the merits will be rejected to and, accordingly, withdrawn from examination.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 2, 3, 7, 8, 9, 11, 12, 13, 18, 19, 20, 22, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formulas Ia, Ih and Ii, wherein X,Y=C (phenyl and naphthyl – no additional ring fusing) R_3 and R_4 forms hydroquinoline. A further election of single disclosed species is required.

II. Claims 1, 2, 3, 7, 8, 10, 11, 18, 21, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formulas Ia and Ih, wherein X=C, Y=N (pyridinyl – no additional ring fusing) R_3 and R_4 forms hydroquinoline. A further election of single disclosed species is required.

III. Claims 1, 2, 3, 7, 14, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula Id (indolyl). A further election of single disclosed species is required.

IV. Claims 1, 2, 3, 7, 15, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula Ie (furanyl). A further election of single disclosed species is required.

V. Claims 1, 2, 3, 7, 16, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula If (indenyl). A further election of single disclosed species is required.

VI. Claims 1, 2, 3, 24, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula Ik, wherein m=0 (dihydroisoindolyl). A further election of single disclosed species is required.

VII. Claims 1, 2, 3, 24, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula Ik, wherein m=2 (benzazepinyl). A further election of single disclosed species is required.

VIII. Claims 1, 2, 3, 24, 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula Ik, wherein m=1 (tetrahydroisoquinolinyl). A further election of single disclosed species is required.

IX. Claims 4-6, 14, 17-23 and 33 and 37 are drawn to compounds and pharmaceutical compositions of Formula I that are not encompassed by Groups I - IX. A further election of single disclosed species is required. This group may be subject to further restriction.

X. Claims 25, 28, 38 and 39 are drawn to a method of inhibiting 11β-hydroxysteroid dehydrogenase in a mammal from one of groups I - IX. An election of species is required if this group is chosen.

XI. Claims 26, 27, 29 and 30 are drawn to a method of controlling glucocorticoid in a mammal from one of groups I - IX. An election of species is required if this group is chosen.

XII. Claims 31 and 32 are drawn to a method of treating diseases and disorders as described by Applicant using one of groups I - IX. An election of species is required if this group is chosen.

XIII. Claims 34-35 are drawn to complex compositions as described by Applicant using one of groups I - IX. An election of species is required if this group is chosen.

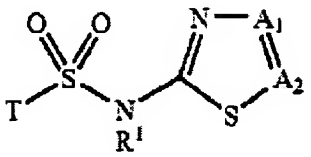
Note: For restriction purposes only, claims 36, 38 and 39 will be considered as claims drawn to methods of treatment and claim 37 will be considered as a claim drawn to compounds.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature corresponding to Group I is a structure of Formula Ia, wherein X,Y=C (phenyl and naphthyl – no additional ring fusing) R_3 and R_4 forms hydroquinoline. Group II contains a structure as its special technical feature, of Formula Ia, wherein X=C, Y=N (pyridinyl – no additional ring fusing) R_3 and R_4 forms hydroquinoline. Group III contains a structure as its special technical feature, wherein of Formula Id (indolyl). Group IV contains a structure as its special technical feature, wherein of Formula Ie (furanyl). Group V contains a structure as its special technical feature, whereiin of Formula If (indenyl). Group VI contains a structure as its special technical feature, wherein of Formula Ik, wherein m=0 (dihydroisoindolyl). Group VII contains a structure as its special technical feature of Formula Ik, wherein m=2 (benzazepinyl). Group VIII contains a structure as its special technical feature of Formula Ik, wherein m=1 (tetrahydroisoquinolinyl). Group IX contains a structure as its special technical feature of Formula I that are not encompassed by Groups I - IX. The ring systems are not considered equivalent.

The method of treating said diseases can be practiced with another materially different product. For example, a class of molecules shown below is used to inhibit 11ß-hydroxsteroid dehydrogenase type 1, may be used in the treatment of diabetes, obesity, and hypertension (see Kurz et al; US 7,074,788 B2).

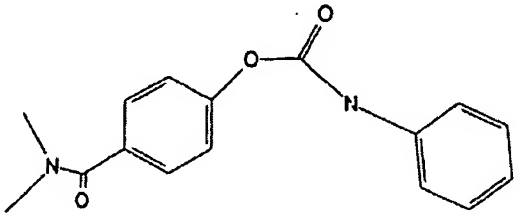


The method of treatment can be practiced with another materially different product. For example, Dow et al uses selective non-steroidal compounds as glucocorticoid receptor modulators (see U.S. 6,380,223 B1). This is just one method of treatment of glucocorticoid receptor modulators.

The method of treatment can be practiced with another materially different product. For example, thienopyridines are compounds used to treat diabetes (see Romines III et al; U.S. 6,833,456 B2). This is just one method of treatment of diabetes.

The technical feature corresponding to the methods claims of Groups X – XII are: a method of inhibiting 11β-hydroxysteroid dehydrogenase, a method of controlling glucocorticoid and a method of treating diseases and disorders as described by Applicant using one of groups I - IX, respectively - found in the individual compound and composition groups above. There is a significant difference in the between compounds/composition and methods of treating a disease/condition and method of inhibition. These treatments of diseases/conditions and compounds/compositions are not considered equivalent.

The special technical feature of this invention is the common core found in Formula I. This special technical feature is found in Monatsh. Chem. 1968, 99, 1799-1807 as described by Schindlbauer et al (see compounds below – reference listed in IDS).



Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

jm

JM

R Desai 12/4/07

RITA DESAI
PRIMARY EXAMINER